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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,774	08/13/2001	Gisela F. Erf	00038	4035

24118 7590 06/03/2003  
HEAD, JOHNSON & KACHIGIAN  
228 W 17TH PLACE  
TULSA, OK 74119

EXAMINER

PARAS JR, PETER

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/913,774

Applicant(s)

ERF ET AL.

Examiner

Peter Paras, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2,3,5 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,3,5 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 2-3, 5 and 15 are pending and are under current consideration. Claims 1, 4, and 6-14 have been cancelled.

### ***Election/Restrictions***

Applicant's election without traverse of Group II, claims 2-3, 5 and 15, in Paper No. 4 is acknowledged.

### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: the oath does not indicate Applicant's priority claim to provisional application 60/176,412 under 35 U.S.C. 119(e); and because the priority claim to parent PCT application PCT/US01/01147 is incorrectly listed under 37 U.S.C. 119, rather than 35 U.S.C. 119.

### ***Drawings***

The drawings filed on 8/13/01 are accepted by the Examiner.

### ***Specification***

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-3 and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed methods with respect to poultry and occlusion of the pulmonary vasculature, does not reasonably provide enablement for the other methods embraced by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are directed to methods of producing a population of animals having increased resistance to pulmonary hypertension (ph), wherein the ph is induced by intravascular particle administration and eliminating the animals susceptible to ph. The claims are further directed to a method of producing improved genetic breeding stocks in animals, comprising occluding the pulmonary vasculature with particulate substances of a size about 8 to 250 micrometers, and separating the ph resistant animals from the ph susceptible animals.

The instant invention features a method of inducing pulmonary hypertension syndrome (phs) in animals, particularly poultry, as a means of separating phs susceptible animals from phs resistant animals, wherein the resistant animals are identified as genetic breeding stocks resistant to phs. The method entails injecting microparticles of about 8-250  $\mu\text{m}$  into the pulmonary vasculature to occlude the

pulmonary vasculature resulting in phs in susceptible animals; the resistant animals do not develop phs. While the instant specification has provided detailed guidance and working examples of identifying and producing phs resistant poultry by such methodology, the instant specification has not provided guidance for identifying and producing other animals resistant to phs. The instant specification also has not provided guidance for inducing phs by occluding vasculature other than pulmonary vasculature. It appears to be unpredictable to induce phs by intravascular injection of particles into vasculature other than pulmonary vasculature. Given the lack of guidance provided by the instant specification it would have required undue experimentation to make and use the invention as claimed.

The claims broadly embrace any species of animal. While the specification has provided guidance for using the claimed methods with respect to poultry the specification has not provided relevant teachings or guidance for practicing the claimed methods with the other animals embraced by the claims. The specification has contemplated that other animals may be used in the claimed methods. However, the specification has failed to recite which other animals could be used when practicing the claimed methods. Moreover, the specification has failed to provide any guidance, working examples, or relevant teachings that would allow the skilled artisan to use animals other than poultry when practicing the claimed invention and the specification has not provided any correlation between use of poultry and any other animals in the claimed methods so that the skilled artisan could extrapolate use of poultry to use of other animals. A mere statement that other animals could be used is not sufficient to

enable the breadth of the methods as directed to any animal. If there is no disclosure of starting material or of any conditions under which claimed process can be carried out, undue experimentation is required, and there is failure to meet enablement requirement that cannot be rectified by asserting that all disclosure related to process is within skill of art. See *Genentech Inc. v. Novo Nordisk A/S* 42 USPQ2d 1001, 1997. In this case the conditions under which the claimed methods can be practiced with animals other than poultry have not been disclosed.

Given the lack of guidance provided by the instant specification for use of animals other than poultry in the claimed methods, it would have required undue experimentation for one skilled in the art to make and/or use the claimed invention.

Note: Amending the claims to read on poultry would be sufficient to overcome this rejection.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is incomplete as written. The claim is directed to a producing a population of animals having increased resistance to pulmonary hypertension. The

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claim is incomplete because the steps of the method do not relate back to the goal of the preamble in a positive process. Appropriate correction is required. Claim 3 depends from claim 2.

Claim 15 is incomplete as written. The claim is incomplete because it lacks a step, which recites induction of pulmonary hypertension in susceptible poultry while resistant poultry remain unaffected. Such a step establishes that poultry are either susceptible or resistant to pulmonary hypertension, such that they can be selected and separated from each other. Appropriate correction is required.

#### **Conclusion**

**No claim is allowed. The claims appear to be free of the prior art of record but are subject to other rejections.**

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

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**PETER PARAS**  
**PATENT EXAMINER**

A handwritten signature in cursive script, appearing to read "Pete Paras", is written below the printed name and title.